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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM12/0225

EXAMINER

ROSE, S

ART UNIT PAPER NUMBER

1614

7

DATE MAILED: 02/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/092504

Applicant(s)

H0065H

Examiner

S. H. H. ROSE

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 1125 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1125 are subject to restriction or election requirement.

### Applicant's Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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Applicant's petition filed November 23, 1998, to make this application special under the provisions of 37 CFR 1.102(c), based on actual infringement has been found to satisfy the provisions set forth in MPEP § 708.02(ii), and, therefore the petition has been granted.

It is an admitted prior art fact, set forth in the record by applicant, on page 3, lines 7-21 of the specification not only that: (a) potassium nitrate is known for desensitizing teeth, to treat dental pain, and to anaesthetize teeth, and for treating gingival and periodontal tissues, and has been admittedly described in dentifrices as a treatment for hypersensitivity, even if not previously described to prevent tooth hypersensitivity in dental tray bleaching compositions, but it is also (b) an admitted prior art fact set forth and introduced into the record by applicant, on page 2 lines 1-3, 7-9 and 22-28 of the specification, and also in the September 1994 Haywood et al. article in Jada Volume 125 cited in the Rembrandt Extra Comfort Non-Sensitizing Bleaching Gel advertisement accompanying the Carley Lyons "statement of facts in support of petition to make special because of actual infringement", that "a majority of bleaching patients experience sensitivity either during or after the bleaching process."

While a technical problem encountered is known, "fact (b)", and applicant's technical solution to this problem is also known,

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"fact (a)", and a reasonable interpretation of 35 U.S.C. § 103 precludes the grant of a valid patent on obvious subject matter by USPTO examiners, it is the policy of the USPTO to give pending U.S. patent application claims their broadest reasonable interpretation, it is further noted that page 5, lines 16-20 intend that the dental bleaching composition of the invention is to be ("can be"), "distinguished from dentifrices", which contain an abrasive and perhaps also a fluoride, applicant has cited prior art describing potassium nitrate and other potassium compounds in peroxide releasing tooth bleaching dentifrices containing a peroxide releasing compound and an abrasive, and, while a concise statement of relevancy of each applicant cited item on the IDS PTO-1449 to the elected species of composition would be helpful in expediting prosecution on the merits, none of claims 1-25 contain any negative proviso to the effect that --said dental bleaching composition is not a dentifrice, and does not contain an abrasive--, and in the absence of said proviso will be in due course rejected on the admitted prior art facts (a) and (b) as evidenced by the cited prior art submitted by applicant, as noted above.

Claims 1-8 do not necessarily even have to be a --dental bleaching gel--, they are recited and required to be "an orally compatible composition", which certainly seems to read on dentifrices comprised of an abrasive and a potassium nitrate ( or

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other potassium compound), and a peroxide releasing tooth bleaching compound.

It is noted that the claims encompass and recite plural species of (a) peroxide releasing tooth bleaching compound (claim 2), (b) potassium compounds, (claims 8, 17, 22, 25), (c) formulations (claim 7), each with or without: (d) carboxypolymethylene (claim 12), (e) hydroxyalkyl cellulose, (claim 13), (f) glycerin, (claims 9, 18), (g) propylene glycol (claim 18), (h) sodium hydroxide, (claim 10).

Claims 1-25 are generic to a plurality of disclosed patentably distinct species comprising

One ultimate species of each of: (a), (b) and (c), and, if further elected, one species of each of: (d), (e), (f), (g) and (h).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, of each even though this requirement is traversed. If this application is filed under Rule 371, the legal authority is PCT Rule 13.2, Annex B, Part 1(f) "Markush Practice"; PCT Rule 13 and 35 U.S.C. § 372, rather than 35 U.S.C. § 121.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of species is required per MPEP § 803, 809.02(d) (Markush group claim practice, separate and burdensome fields of search required).

Patentably distinct Markush species are independent inventions, In re Webber, 198 USPQ 328, In re Haas, 198 USPQ 334. Divisional applications may be filed under 35 U.S.C. § 121, as a result of an Office requirement for an election of a patentably distinct species as made herein. In re Joyce, 115 USPQ 412, In re Herrick, 115 USPQ 412. This satisfies the "patentably distinct" criterion since the Examiner is not of the opinion that the various species are obviously unpatentable over one another, and each species (as noted above) is capable of independent manufacture, use, and sale, with the other components of the claimed formulations.

Applicant is further required to identify the claims that correspond to the elections as well as those that do not even if the requirements are traversed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Shep Rose  
Senior Primary Examiner  
Art Unit 1614

SKR:cdc  
February 24, 1999

**SHEP K. ROSE  
PRIMARY EXAMINER  
GROUP 1200**